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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 98,541-C)

In the Application of:

Kimberly Christensen

Serial No.: 09/721,096

Filing Date: November 22, 2000

For: Removal Of Embedding Media From Biological Samples and Cell Conditioning on Automated Staining Instruments

Examiner: Yalena G. Gakh

Group Art Unit: 1743

Confirmation No. 4217

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

Dear Sir:

I, Kimberley Christensen, residing at 5742 East Waverly, Tucson AZ 85712, hereby declare:

1. I am a named co-inventor on United States Patent Application Serial No. 10/320219, filed on December 16, 2002 which claims a method of Removal Of Embedding Media From Biological Samples and Cell Conditioning on Automated Staining Instruments This patent application was filed on behalf of and is assigned to Ventana Medical Systems, Inc. ("Ventana").

2. I hold a Masters degree in Physical Chemistry from the University of Arizona.

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3. I am currently the Manager of the Systems Integration Group at Ventana Medical Systems Inc. (Ventana). I have worked at Ventana for 11 ½ years. During that time I have worked with automated laboratory systems in various areas including development and detection chemistry, application trouble-shooting, instrumentation design, and instrumentation development.

4. I have reviewed the specification of the above-captioned patent application, I have reviewed the Official Action issued by the Examiner in this application on January 12, 2004 and I have reviewed the Protocol "Ziehl-Neelsen Stain For ABF" http://medlib.med.utah.edu/Webpath/HISTHTML/MANUALS/ZIEHL.pdf reference (hereinafter "the Ziehl-Neelsen Protocol") cited by the Examiner in the Official Action.

5. The section of the Ziehl-Neelsen Protocol titled "METHOD" lists steps of an AFB staining method. Step 1 reads: "Heat slides in slide dryer to facilitate dewaxing" and Step 2 reads" "Take sections to water." Based upon my experience in the biological sample analysis art, one of ordinary skill in the art would understand these steps to involve a dewaxing technique that uses an organic solvent such as xylene.

6. Step 1 of the Ziehl-Neelsen Protocol states "1 – heating slides in a slide dryer." One of ordinary skill in the art would understand step 1 to refer to a procedure that takes place before the dewaxing step. Step 2 of the Ziehl-Neelsen Protocol states: "2. Take samples to water". One of ordinary skill in the art would also understand step 2 to refer to a step that takes place after a solvent dewaxing step. In a solvent dewaxing step, wax-embedded biological samples are contacted with a solvent such as xylene in order to dissolve the wax. Afterwards, the dewaxed biological sample is

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washed with alcohol to remove the unwanted xylene solvent. The biological sample includes essentially no water following the alcohol wash. Therefore, the sample has to be rehydrated with water following solvent dewaxing. Therefore, the term "taking the sections to water" would be understood by persons of ordinary skill in the art to refer to a sample rehydration step that is required following solvent dewaxing. For this reason, Steps 1 and 2 of the Ziehl-Neelsen Protocol only make sense if the steps are used in conjunction with a solvent dewaxing procedure.

7. I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 6/14/04 Signed: ______________________

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